August 16, 2022

RCE Monthly Informational Call

Mariann Yeager, CEO, The Sequoia Project; RCE Lead
Zoe Barber, Director, Policy, The Sequoia Project
Johnathan Coleman, RCE CISO
Alan Swenson, Executive Director, Carequality
Chantal Worzala, Principal, Alazro Consulting
This program is supported by the Office of the National Coordinator for Health Information Technology (ONC) of the U.S. Department of Health and Human Services (HHS) under grant number 90AX0026, Trusted Exchange Framework and Common Agreement - Recognized Coordinating Entity (RCE) Cooperative Agreement Program, in the amount of $2,919,000 with 100 percent funded by ONC/HHS. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by ONC, HHS or the U.S. Government.
Agenda

- How will Exchange Work under TEFCA?
- What are TEFCA Components?
- Timeline to Operationalize TEFCA
- Questions & Answers: Part 1
  » Questions received during or after July monthly call
- SOP Status & Release Schedule
  » Recently Released SOPs and Resources
- Payment and Health Care Operations Stakeholder Input Process
- Questions & Answers: Part 2
  » Questions received during August monthly call
How will exchange work under TEFCA?

ONC defines overall policy and certain governance requirements.

RCE provides oversight and governing approach for QHINs.

Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.

Each QHIN connects Participants, which connect Subparticipants.
TEFCA Components

- Trusted Exchange Framework
- Common Agreement
- Standard Operating Procedures
- QHIN Technical Framework
- QHIN Onboarding
- Metrics
- Governing Approach
Timeline to Operationalize TEFCA

2021
- Public engagement
- Common Agreement Work Group sessions
- RCE and ONC use feedback to finalize TEFCA

Summer/Fall 2022*
- Finalize initial SOPs
- QHINs begin signing Common Agreement and applying for Designation

2023
- Establish Governing Council
- Follow change management process to iterate Common Agreement, SOPs, and QTF, including to support FHIR-based exchange

Q1 of 2022
- Publish Common Agreement Version 1
- Publish QHIN Technical Framework (QTF) Version 1 and FHIR Roadmap
- Initiate work to enable FHIR-based exchange
- Public education and engagement

Q3 and Q4 of 2022
- Onboarding of initial QHINs
- Additional QHIN applications processed
- RCE establishes Transitional Council
- RCE begins designating QHINs to share data
- Prepare for TEFCA FHIR exchange pilots

*Updated per ONC Buzz Blog post, May 16, 2022
SOP Status & Release Schedule
## TEFCA SOP Release Schedule

<table>
<thead>
<tr>
<th>SOP Name</th>
<th>Expected Publication of Version 1 Final</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QHIN Security Requirements for the Protection of TI (Update)</strong></td>
<td>Version 1.1 released 5/16</td>
</tr>
<tr>
<td><strong>Exchange Purposes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>QHIN Fee Schedule (Schedule 1)</strong></td>
<td>June 2022 (V1 released 6/21)</td>
</tr>
<tr>
<td><strong>Types of Entities That Can Be a Participant or Subparticipant in TEFCA</strong></td>
<td>July 2022 (V1 released 7/19)</td>
</tr>
<tr>
<td><strong>QHIN Onboarding &amp; Designation (and QHIN Application)</strong></td>
<td>August 2022 (Draft released 5/16)</td>
</tr>
<tr>
<td><strong>Means to Demonstrate U.S. Ownership and Control of a QHIN</strong></td>
<td>August 2022 (Draft released 6/30)</td>
</tr>
<tr>
<td><strong>Individual Access Services (IAS) Exchange Purpose Implementation</strong></td>
<td>August 2022 (Draft released 6/30)</td>
</tr>
<tr>
<td><strong>Participant and Subparticipant Security</strong></td>
<td>October 2022</td>
</tr>
<tr>
<td><strong>Other Security Incidents and Reportable Events</strong></td>
<td>End of 2022</td>
</tr>
<tr>
<td><strong>Payment and Health Care Operations Exchange Purpose Implementation</strong></td>
<td>Early 2023</td>
</tr>
<tr>
<td><strong>Public Health Exchange Purpose Implementation</strong></td>
<td>Early 2023</td>
</tr>
<tr>
<td><strong>Government Benefits Determination Exchange Purpose Implementation</strong></td>
<td>Mid 2023</td>
</tr>
<tr>
<td><strong>Suspensions Process</strong></td>
<td>2023</td>
</tr>
<tr>
<td><strong>Successor RCE &amp; Transition</strong></td>
<td>2023</td>
</tr>
</tbody>
</table>
Draft SOP: Individual Access Services (IAS) Exchange Purpose Implementation

Stakeholder Feedback
Demographics-based matching at a national network scale poses challenges for responding to Individual Access Services queries

The threat of potential penalties in the event of a breach - and having to inform individuals and HHS - is an obstacle to facilitating individual access through HIEs and the TEFCA using the same infrastructure used today to support treatment queries

Need formal guidance or enforcement discretion from HHS or there will be significant adverse consequences to achieving nationwide interoperability and patient access

Support for OAuth as the technical method for patient matching for IAS requests in TEFCA when FHIR is ready

Support for the use of CSPs who are IAL2 certified as being the ‘source of truth’ for individual’s demographic data

Greater education about how Credential Service Providers interact with Covered Entities

Recommendations to separate attributes for ID verification (IAL2) that can be validated from additional patient matching components
Draft SOP: Means to Demonstrate U.S. Ownership and Control of a QHIN

Stakeholder Feedback
Draft SOP: Means to Demonstrate U.S. Ownership and Control of a QHIN: Stakeholder Feedback

This SOP sets forth the means by which an entity seeking to be Designated as a QHIN shall demonstrate that it satisfies the requirements of Section 4.1(i) of the Common Agreement. It also identifies the parameters under which a QHIN may permissibly have limited ownership or control by Non-U.S. Individual(s) or Non-U.S. Entity(ies).

- Provide additional consideration to companies that are trusted by the United States, both by government entities and private healthcare providers, to provide services in connection with the U.S. healthcare system, and that have in place the protocols required to protect highly sensitive healthcare data as vetted by U.S. government and private entities.
- Consider increasing the ownership percentage that would be of concern.
- Why is ownership by a non-US Individual treated differently than ownership by a non-US Entity?
- Publish more information related to how a 5% standard was chosen.
- Requirements may pose practical and operational challenges for publicly traded companies.
- Enumerate what factors will be considered in the case-by-case analysis.
- Certain questions on Foreign Control may limit an applicant’s ability to license technology from a non-US Entity or raise questions about the ownership status of their Participants.
Additional Topics for Stakeholder Feedback

Draft SOP: QHIN Onboarding & Designation and Draft QHIN Application
1. Based on stakeholder feedback, the RCE is considering adding a new term to the QHIN Onboarding & Designation SOP and QHIN Application to differentiate between an applicant’s current network and the network it will use to provide Connectivity Services per the Common Agreement, if that network is different than the current network. We request stakeholder feedback on the need for this additional term, ideas for alternative terms to describe the “Connectivity Services Network”.

2. The draft QHIN Application and draft QHIN Onboarding & Designation SOP asked applicants to submit average monthly and annual transaction volumes for each Exchange Purpose they currently support, in order to demonstrate their ability to successfully process a high number of transactions through a high-performing, reliable environment. In an effort to make the application more objective and measurable, the RCE is seeking feedback on draft language to define: 1) transaction volumes expected from the current network an applicant operates at the time of application, and 2) transaction volumes a QHIN should be required to support through its Connectivity Services Network and how the applicant plans to scale their current network to meet this volume.

3. The draft QHIN Onboarding and Designation SOP requires that a QHIN’s network governance structure provides for participation by network Participants. The RCE understands that a QHIN may not immediately, upon Designation, have network Participants onboarded for representation on its governing body. Therefore, we are proposing to add a “Provisional Governance Status,” which would provide QHINs with up to 12 months from Designation to onboard Participants and meet the requirements for participatory and representative governance. The RCE requests feedback on the necessity of this Provisional Governance Status; ideas for alternative terms to describe the status, if “Provisional Governance Status” is unclear to stakeholders; and the draft language below.

*The RCE is seeking stakeholder input on the following topics through August 17, 2022. The online submission form for feedback is available on the RCE website.*
Payment & Health Care Operations Stakeholder Input Process
Payment & Health Care Operations Input Process

Charge
• Collect stakeholder input to inform the first version of the TEFCA P&HCO Exchange Purpose Implementation SOP to be published by early 2023.

Priorities for Use Case Selection
• High benefit, high burden
• Strong likelihood of voluntary adoption
• Increase patient access and interoperability
• Reduce provider/payer burden

Initial Use Case(s)
• Risk Adjustment and Quality Management
  » Payment & HCO components
    – Revenue normalization
    – Resource utilization
    – Gaps in care
    – Quality measurement
Level Set On Where the Market and TEFCA Are Today

• Current market for payment & health care operations
  » Commercial market for P&HCO data exchange services
  » Challenges with identifying and collecting the “right” data
    – Minimum necessary concerns
    – Challenges with data tagging and segmentation (e.g., for self-pay or sensitive data)
    – Primary source verification requirements
  » Trust is hard to build - Divergent interests among payers and providers
  » Value proposition on both sides not always clear
  » Unintended consequences (e.g., pre-mature denials)

• Current TEFCA environment
  » TEFCA will initially operate in an IHE environment – eventually move to FHIR
  » Exchange modalities include Query Solicitation and Message Delivery
  » TEFCA prohibits fees between QHINs but is silent on other fees
Guiding Principles

- Improve **transparency** of why the data is being requested
- Enable **reciprocity** between participant types - shared value
- Provide the **right information** and nothing more (minimum necessary)
- Provide **consistent** information
- Be **transport agnostic**
- Support **integration into existing workflows**
- Account for both **EHR and non-EHR technologies**
- Get to **win-win-wins** (patient, provider, payer)
  - Patient at the center
  - Reducing payer and provider burden
- Require **no special effort**
- **Contain costs**
Payment and Health Care Operations SOP Outline

• Definition
• Permitted Actors and Workflows
• Request
  • Guidelines around specifying sub purpose of use
  • Date range
  • Member information
  • Other information about why the data is needed
  • Guidelines around Message Delivery
• Responses
  • What formats do payers/providers need in a response?
  • What types of information (content) do providers/payers need?
  • Whose responsibility is it to determine what data should be sent?
  • Optionality
• Directory
  • How do you ensure transparency around who the original requestor is?
  • How do you verify the relationship with the requestor?
Educational Resources

Resources

- Common Agreement v. 1
- QHIN Technical Framework
- FHIRE® Roadmap for TEFCA
- Standard Operating Procedures
- User’s Guide
- Benefits of TEFCA by Stakeholder Factsheets
- FAQs

https://rce.sequoiaproject.org/tefca-and-rce-resources/

Additional Resources:
https://www.healthit.gov/tefca

All Events and Recordings: https://rce.sequoiaproject.org/community-engagement/
Questions & Answers

For more information: rce.sequoiaproject.org